

REMARKS

Claims 22-42 are pending in the present application. Claims 22-32 have been amended. Claims 33-42 have been presented herewith.

Claim Rejections-35 U.S.C. 112

Claim 31 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is respectfully traversed for the following reasons.

The Examiner has alleged that it is unclear how the deviation of the orifice diameter in claim 31 is determined. The Examiner has asserted that "a longitudinal axis" could be any number of axes depending on where they are drawn, and that in such a case, the percentages claimed would correspond to different values for each axis, causing the actual values to be indefinite. Applicants respectfully disagree for the following reasons.

Claim 31 features that "deviation of the orifice diameter along a longitudinal axis of the orifice ranges from +/- 1% to +/- 10%, whereby a substantially homogeneous electrical field is provided at a center of the orifice".

Claims 31 thus features that the orifice diameter has a longitudinal axis, and that the deviation of the orifice diameter at this longitudinal axis is within the stated range. Claim 31 does not feature that the stated deviation of the orifice diameter is for a number of axes. That is, a longitudinal axis is claimed. Since claim 31 does not feature plural axes, and since the percentages as claimed correspond to the longitudinal axis,

the scope of claim 31 should be clear. Accordingly, Applicants respectfully submit that claim 31 is in compliance with 35 U.S.C. 112, second paragraph, and thus respectfully urge the Examiner to withdraw this rejection. Any further amendment of claim 31 would unnecessarily narrow claim scope.

Claim Rejections-35 U.S.C. 103

Claims 22-29, 31 and 32 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Hanss et al. reference (U.S. Patent No. 4,835,457) in view of the Graham reference (U.S. Patent No. 6,111,398). This rejection, insofar as it may pertain to the presently pending claims, is traversed for the following reasons.

The electrical impedance cell counting apparatus of claim 22 counts and characterizes particles suspended in a liquid, and includes in combination among other features a mixing chamber and a collection chamber separated by a polymer membrane containing an orifice for passage of the particles, wherein a diameter of the orifice is in a range of 10 μm to 1000 μm ; and a volume meter that determines a period during which a fixed volume of the liquid passes through the orifice. Applicants respectfully submit that the electrical impedance cell counting apparatus of claim 22 would not have been obvious in view of the prior art as relied upon by the Examiner for at least the following reasons.

The Hanss et al. reference as primarily relied upon provides an apparatus for determining the deformability of red blood corpuscles using a filtration method, and

measuring the transit time of the corpuscles by means of electrical impedance variations. As described beginning in column 3, line 9 of the Hanss et al. reference, during the whole time corresponding to a passage of the red corpuscle through a pore, the electric resistance of the membrane is increased. The result is an electric pulse of duration substantially equal to that of the passage of the red corpuscle through the filter. This duration is called transit time of the red corpuscle. The greater the rigidity of the red corpuscle, the longer the transit time and the longer the corresponding pulse. As further described beginning in column 4, line 65 of the Hanss et al. reference, the electric impedance variations are translated into transit times, the pulses obtained are displayed as shown in Fig. 4, and histograms are obtained corresponding to the distribution of the rheological properties of the red blood corpuscles.

Applicants respectfully submit that the Hanss et al. reference does not disclose a volume meter that determines a period during which a fixed volume of the liquid passes through the orifice. This should be especially clear, because the Hanss et al. reference provides an apparatus for determining the deformability of red corpuscles, and is not an electrical impedance cell counting apparatus for counting particles suspended in a liquid. That is, in order to count particles suspended in a liquid, determination of a fixed volume of liquid passing through the orifice is necessary. The Hanss et al. reference as primarily relied upon does not disclose such features. The Hanss et al. reference thus does not disclose an electrical impedance cell counting apparatus.

The Examiner has secondarily relied upon the Graham reference as indicated at the bottom of page 5 of the Final Office Action dated December 22, 2008, for the purpose of showing conduit diameter. However, volumeter conduit 10 described with respect to the structure in prior art Fig. 1 of the Graham reference is not disclosed as deforming red corpuscles or particles. Moreover, the conduit as described in column 3 of the Graham reference as relied upon by the Examiner is described specifically in columns 1 and 2 as a thin wafer W made of a homogeneous dielectric material, not specifically as polymer membrane. As additionally described beginning in column 2, line 36 of the Graham reference, the thin wafer W may be cut from capillary tubing, or in the alternative ruby or sapphire ring jewels are frequently used as the conduit wafer W.

Incidentally, volumeter assembly 50 as shown in the Fig. 7 preferred embodiment of the Graham reference is described beginning in column 25, line 30 as a complex assembly including element 51 having substantial electrical resistivity preferably made from a dielectric such as ruby, sapphire, alumina, beryllia, synthetic quartz, a conductive glass, a conductive ceramic or a type of conductive polymer or plastic. In contrast, elements 52 and 53 of volumeter assembly 50 are required to have substantially lower resistivity and are preferably metal, or alloys from the platinum group or conductive ceramic such as titanium, tungsten or silicon carbides. Other metals such as gold, silver, titanium tantalum, tungsten, nickel, copper, alumina or various alloys are also described. The preferred embodiment of the Graham reference thus discloses a

complex and expensive laminated multilayer assembly, not a polymer membrane containing an orifice as featured in claim 22. One of ordinary skill thus would have no motivation to modify the apparatus for measuring deformability of the Hanss et al. reference in view of the Graham reference. Accordingly, Applicants respectfully submit that the electrical impedance cell counting apparatus of claim 22 would not have been obvious in view of the prior art as relied upon by the Examiner taken singularly or together, and that this rejection, insofar as it may pertain to claims 22-29, 31 and 32, is improper for at least these reasons.

Claim 29, as dependent upon claim 22, features that the membrane is positioned in a single-use cartridge. With respect to claim 9, the Examiner has asserted on page 7 of the Final Office Action that the apparatus of the Hanss et al. reference could be intended for "single use" by the user, and that claim 29 is thus obvious. Applicants respectfully disagree for the following reasons.

Applicants respectfully submit that the Hanss et al. and Graham references do not disclose or even remotely suggest apparatuses that are positioned in a cartridge. Moreover, the Hanss et al. and Graham references do not disclose or even remotely suggest apparatuses that are single use cartridges. The Examiner has asserted that the apparatus of the Hanss et al. reference "could be" intended for "single use". However, in absence of such disclosure or suggestion as drawn directly from the relied upon Hanss et al. and Graham references, the rejection of claim 29 would appear to be based on impermissible hindsight. Accordingly, Applicants respectfully submit that the

electrical impedance cell counting apparatus of claim 29 would not have been obvious in view of the prior art as relied upon by the Examiner taken singularly or together, and that this rejection, insofar as it may pertain to claim 29, is improper for at least these additional reasons.

Claim 30 has been rejected under 35 U.S.C. 103(a) as being unpatentable over the Hanss et al. and Graham references, in further view of the Berndtsson et al. reference (WO99/01742). Applicants respectfully submit that the apparatus of the Berndtsson et al. reference does not include a polymer membrane containing an orifice, and thus does not overcome the above noted deficiencies of the primarily relied upon prior art. Accordingly, Applicants respectfully submit that claim 30 would not have been obvious in view of the prior art as relied upon by the Examiner taken singularly or together, and that this rejection of claim 30 is improper for at least these reasons.

Claims 33-41

The electrical impedance cell counting apparatus for counting and characterizing particles suspended in a liquid of claim 33 includes in combination among other features a housing with a mixing chamber and a collection chamber separated by a polymer membrane containing an orifice, wherein a diameter of the orifice is in a range from 10 μm to 1000 μm , and wherein a diameter of the particles is not greater than 60 percent of the diameter of the orifice".

As emphasized previously, the primarily relied upon Hanss et al. reference is an apparatus for determining the deformability of red corpuscles in blood. As described in column 1, lines 15-16 of the Hanss et al. reference, the red corpuscles have a diameter of about 7.5 μm . As further described in column 5, lines 13-15 of the Hanss et al. reference, the average diameter of the pores is about 5 μm . This relationship is necessary in the Hanss et al. reference to deform red corpuscles passing through the pores of the filtering membrane. The red corpuscles in the primarily relied upon Hanss et al. reference thus can not have a diameter not greater than 60 percent of a diameter of the pores, as featured in claim 33. Moreover, even if proper motivation existed for modifying the size of the membrane pores of the Hanss et al. reference to be larger (which motivation Applicants do not admit exists), the modified structure could not have the above noted relationship between particle diameter and pore diameter as featured in claim 33 and at the same time deform such larger cells. Applicants thus respectfully submit that claims 33-40 would not have been obvious in view of the prior art as relied upon by the Examiner for at least these reasons.

Claim 41 is a single-use disposable electrical impedance cell counting cartridge for counting and characterizing particles suspended in a liquid, and includes in combination among other features a mixing chamber and a collection chamber separated by a polymer membrane containing an orifice.

Applicants respectfully emphasize that only the Berndtsson et al. reference as relied upon by the Examiner discloses a disposable sampling device. However,

housing 40 as shown in Fig. 2 of the Berndtsson et al. reference as relied upon does not include an orifice within a membrane. There would be no motivation within the relied upon prior art to modify the structure of the Berndtsson et al. reference to include a polymer membrane. Accordingly, Applicants respectfully submit that claims 41 and 42 would not have been obvious in view of the prior art as relied upon by the Examiner taken singularly or together for at least these reasons.

Conclusion

The Examiner is respectfully requested to reconsider and withdraw the corresponding rejections, and to pass the claims of the present application to issue, for at least the above reasons.

In the event that there are any outstanding matters remaining in the present application, please contact Andrew J. Telesz, Jr. (Reg. No. 33,581) at (571) 283-0720 in the Washington, D.C. area, to discuss these matters.

Pursuant to the provisions of 37 C.F.R. 1.17 and 1.136(a), the Applicants hereby petition for an extension of two (2) additional months to June 22, 2009, for the period in which to file a response to the outstanding Office Action. The required fee of \$490.00 should be charged to Deposit Account No. 50-0238.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment for any additional fees that may be required, or credit any overpayment, to Deposit Account No. 50-0238.

Respectfully submitted,

VOLENTINE & WHITT, P.L.L.C.

A handwritten signature in black ink, appearing to read 'Andrew J. Telesz, Jr.', with a stylized flourish at the end.

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